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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,981	08/29/2005	Lionel Vedrine	P-5753	5214
7590 David W Hightet Becton Dickinson and Company 1 Becton Drive-MC 110 Franklin Lakes, NJ 07417			EXAMINER MEHTA, BHISMA	
			ART UNIT 3767	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,981

Applicant(s)

VEDRINE, LIONEL

Examiner

BHISMA MEHTA

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-7 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the respective means for operating said means of holding the needle in position and said means of holding the container must be shown or the feature(s) canceled from the claim(s). The peripheral portion of the piston which is deflected into the blind hole must be shown or the feature(s) canceled from the claim(s). The needle-supporting part with at least one locking means must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. It is unclear where these features are shown as the language used in the claims is not consistent with the language which is used in the specification for the description of the figures. Even though Applicant has indicated that the respective means for operating said means of holding the needle in position and said means of holding the container is the walls (32 and 42) as disclosed in paragraph [0057] of the specification, there is no specific reference in the disclosure that the respective means are these structural components. The respective means for operating said means of holding the needle in position and said means of holding the container need to be defined as the walls (32 and 42) in the specification. As for the needle-supporting part with at least one locking means, no portion or component of the device has been defined as the needle-supporting part which therefore makes it difficult to ascertain where the needle-supporting part is shown in the drawings.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Applicant has not explicitly stated what structure of the device performs the function recited with regards to the respective means for operating said means of holding the needle in position and said means of holding the container. It appears from Applicant's remarks in lines 12-17 of page 8 of

the Remarks filed April 10 2008 that the respective means for operating said means of holding the needle in position and said means of holding the container are the walls (32 and 42) in the specification. Therefore, the respective means for operating said means of holding the needle in position and said means of holding the container need to be defined as the walls (32 and 42) in the specification. Similarly, the structure corresponding to the spring means for moving the needle and the container to the retracted position and the locking means of the needle-supporting part needs to be defined in the specification. Appropriate correction is required.

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the piston being so shaped to have a blind hole located adjacent a peripheral portion and where the peripheral portion of the piston is deflected into the blind hole so as to allow the product to pass between the piston and the container.

Claim Objections

4. Claims 1 and 5-8 are objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification. The specific means-plus-function being objected to is the respective means for operating said means of holding the needle in position and said means of holding the container of claim 1, the

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spring means for moving the needle and the container to the retracted position of claim 5, and the locking means of claim 7. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al (U.S. Patent No. 6,981,963) in view of Pfleger (U.S. Patent No. 4,929,230). Barker et al disclose a device for injecting a product having a body (130) with a hollow injection needle (112) and a container (150) containing the injectable product. The device also has a plunger (140) that slides in the body. The container (150) is closed at one end and is connected to the plunger (140). Means for holding the needle in position and means for holding the container on the forward end of the container are provided on the device. Barker et al also disclose the device as including a piston (170) engaged in the container which is so shaped that, in a first configuration, closes the container and, in a second configuration, allows product to pass out of the container between itself and the container without the piston being pierced. The piston is spaced from, and not in contiguous contact with, the needle (112) with the piston being in the second configuration or position (Figure 16). Respective means for operating said means of holding the needle in position and said means of holding the

container in position are in the form of the displacement of the needle retainer (120) along with the release of the container or the clip (200) (lines 33-40 of column 13 and Figures 12-16). The piston (170) in the second configuration as shown in Figures 14 and 15 allows the product to pass between the piston and the container. Barker et al also disclose the device as having spring means (126). The body forms a distal end perpendicular to the axis of the needle, from which the needle projects. As to claim 7, the means for holding the needle in position comprise a needle-supporting part with at least one locking means in the form of the apertures (38 in Figure 5, also shown in Figure 13 at 126) and at least one tab (24 in Figure 6, 120 in Figure 12) that comprises a locking means, in the form of the protrusions of the tabs, able to engage with that of the needle-supporting part. The tabs (24 or 120) are moveable radially between a normal, radially inward position as seen in Figure 15 and a radially outward position, as seen in Figure 16, where a zone of the plunger moves the tab radially out.

Barker et al disclose the device substantially as claimed. However, Barker et al are silent on the specifics of the piston being so shaped to have a blind hole located adjacent a peripheral portion where the peripheral portion of the piston is deflected into the blind hole to allow the product to pass between the piston and the container. Pfleger disclose an injection device having a piston (33) engaged in a container (20) where the piston has a blind hole (48) located adjacent a peripheral portion (36) which is deflected to allow product to pass between the piston and the container and out of the container without the piston being pierced. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the piston of

Barker et al with the piston having a blind hole located adjacent a peripheral portion as taught by Pfleger as Pfleger teaches that it is well known to use a piston with a blind hole and a peripheral portion that can be deflected to allow the flow of a product between the piston and the container. Since the use of the piston of Pfleger does not require and would not work with the fluid passage (160) of Barker et al, it would be obvious to one having ordinary skill at the time the invention was made that the substitution of the piston of Barker et al with the piston of Pfleger would not require and would not work with a fluid passage, and thus the device of Barker et al would be modified to not include this fluid passage.

Allowable Subject Matter

7. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments with respect to claims 1 and 5-7 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-

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3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/

Examiner, Art Unit 3767

/Kevin C. Simons/

Supervisory Patent Examiner, Art Unit 3767